DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-5, 8 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin (US 20050272169) in view of Schnipelsky (US 5229297).

With respect to claim 1, Griffin discloses a biochemical cartridge comprising a reaction portion (Figure 1:14) that includes a plurality of chambers (Figure 1:16, 18, 17, 20) and a plurality of channels (Figure 1:15). A solution storage portion (Figure 1:12) is isolated and separated above the reaction portion. A penetrable portioning member (Figure 1:13) is disposed between the solution storage portion and the reaction portion so as to move the solution from the solution storage portion to the chamber of the reaction portion. This is disclosed in paragraphs [0009]-[0012] and [0084]-[0094]. Paragraphs [0034] and [0051] state that the solution storage portion and the reaction portion are constructed as independent articles that are brought together only at a time when the apparatus is in use. Paragraph [0044] states that the portions are reversibly coupled together using a mechanical clamping mechanism. Paragraphs [0030] and [0088] indicate that any one of the many chambers of the reaction portion may or may not contain a dried reagent. Griffin further discloses in paragraphs [0085] and [0086] that the reaction portion (14) includes a supply port (17) facing the storage portion (12) but not covered by the storage portion during use. The port opening (23) is unobstructed by a flap means (24) at the time of use.

However, Griffin does not expressly state that the reaction portion includes a port at a side surface for permitting access to the chambers. Although Griffin does indicate in paragraph [0011] that fluidic ports may be positioned in either the reaction portion or

the solution storage portion, Griffin does not disclose expressly describe a port positioned at a reaction portion side surface.

Schnipelsky discloses a biochemical reaction cartridge comprising a reaction portion (Figure 7:10B) holding a plurality of solution storage portions (Figure 7:30B, 32B, 34B, 36B, 38B) and a reaction chamber (Figure 7:40B). This is disclosed in column 9, line 62 to column 10, line 46. Schnipelsky states that fluids are moved to the reaction chamber from the solution storage portions. Schnipelsky additionally states that fluid is also moved to the reaction chamber through a port (Figure 7:22A) constructed at the sidewall of the reaction chamber.

Griffin and Schnipelsky are analogous art because they are from the same field of endeavor regarding biochemical reaction cartridges.

At the time of the invention, it would have been obvious to form a fluid port along the exterior walls of the Griffin reaction portion. Griffin contemplates doing exactly this in paragraph [0011] stating "an inlet in either the [reaction portion] or the [solution storage portion] into which a sample to be analyzed can, in use, be placed." Schnipelsky further is provided as evidence that it is known in the art to construct a fluid port along the sidewall of a reaction portion. Schnipelsky teaches that fluid moves to the reaction chamber from not only solution storage chambers, but also from a fluid port fabricated at the sidewall of a reaction portion. Accordingly, one of ordinary skill in the art would have been motivated to move fluid to the Griffin reaction chamber simultaneously from the disclosed plurality of solution storage portions, as well as from fluid ports located along the sidewalls of the Griffin reaction portion.

With respect to claims 2 and 3, Griffin and Schnipelsky disclose the apparatus in claim 1 wherein the partition member is penetrable by pushing with a valve stem. In paragraphs [0096] and [0097], Griffin teaches that a piercing pin (Figure 3:145) and a plunger (Figure 1:130) are used to penetrate the partition member. The piercing pin is fully capable of acting as a valve stem that seals the hole through the partition member by being pushed to a second-stage.

With respect to claims 4 and 5, Griffin and Schnipelsky disclose the apparatus set forth in claim 3 as set forth in the 35 U.S.C. 103 rejections above. Griffin additionally teaches in paragraphs [0096] and [0097] that the needles (Figure 3:145) are moved using a pressing rod (Figure 3:130). Griffin does not expressly disclose that multiple pressing rods of differing lengths are used to determine how far the needles are allowed to penetrate into the partition member (Figure 3:113). However, simple changes to the shape and size of a structure are not considered to be patentable distinctions over the prior art. At the time of the invention, it would have been obvious to utilize pressing rods that are of a suitable length. The length of the pressing rods is considered to be a result effective variable that is optimized through routine experimentation. See MPEP 2144.04 and 2144.05.

With respect to claim 8, Griffin and Schnipelsky disclose the invention as set forth in the rejections above. Additionally, Griffin teaches that solutions contained in a plurality of chambers (Figure 1:22) on the solution storage portion (Figure 1:12) are

independently moved through the partition member (Figure 1:13) and collected in corresponding chambers (Figure 1:116) of the reaction portion (Figure 1:14). Each solution is moved via channels (Figure 1:15) to a central reaction area (Figure 1:18) in order to facilitate the detection of analytes. Griffin, however, teaches that the same partition member is punctured multiple times. Griffin does not indicate that each solution storage portion chamber is associated with a separate partition member.

At the time of the invention, it would have been obvious to divide the comprehensive partition member disclosed Griffin into a plurality of smaller partition members each selectively associated with a specific solution storage chamber. This would have been beneficial because it would have ensured that defects in one partitioning area do not affect the operation of the device in other partitioning areas. The separation of a large structure into a plurality of smaller structures characterized by identical properties is generally not considered to be a patentable improvement over the prior art. See MPEP 2144.04.

With respect to claim 11, Griffin and Schnipelsky disclose a biochemical treatment apparatus comprising an accommodation unit in which a biochemical reaction cartridge including a reaction portion (Figure 1:14) and a solution storage portion (Figure 1:12) are mounted. The reaction and solution storage portions each have a plurality of chambers that correspond to one another such that reagents from the storage portion are collected in the reaction portion following the activation of a driving means (Figure 3:145). The driving means penetrates a partition member (Figure 1:13)

of the biochemical reaction cartridge mounted in the accommodation unit. Various reaction treatment means are provided for causing the rupture of the partition member. The partition member can be broken due to the pumping of excess fluids to the chambers of the solution storage portion, or through the mechanical activation of a plunger (Figure 3:130). This is described in paragraphs [0084]-[0098]. Paragraph [0090] states that a control means in the form of a microprocessor is provided for regulating the motion of the driving means.

However, Griffin does not expressly state that the reaction portion includes a port at a side surface for permitting access to the chambers. Although Griffin does indicate in paragraph [0011] that fluidic ports may be positioned in either the reaction portion or the solution storage portion, Griffin does not disclose expressly describe a port positioned at a reaction portion side surface.

Schnipelsky discloses a biochemical reaction cartridge comprising a reaction portion (Figure 7:10B) holding a plurality of solution storage portions (Figure 7:30B, 32B, 34B, 36B, 38B) and a reaction chamber (Figure 7:40B). This is disclosed in column 9, line 62 to column 10, line 46. Schnipelsky states that fluids are moved to the reaction chamber from the solution storage portions. Schnipelsky additionally states that fluid is also moved to the reaction chamber through a port (Figure 7:22A) constructed at the sidewall of the reaction chamber.

Griffin and Schnipelsky are analogous art because they are from the same field of endeavor regarding biochemical reaction cartridges.

At the time of the invention, it would have been obvious to form a fluid port along the exterior walls of the Griffin reaction portion. Griffin contemplates doing exactly this in paragraph [0011] stating "an inlet in either the [reaction portion] or the [solution storage portion] into which a sample to be analyzed can, in use, be placed." Schnipelsky further is provided as evidence that it is known in the art to construct a fluid port along the sidewall of a reaction portion. Schnipelsky teaches that fluid moves to the reaction chamber from not only solution storage chambers, but also from a fluid port fabricated at the sidewall of a reaction portion. Accordingly, one of ordinary skill in the art would have been motivated to move fluid to the Griffin reaction chamber simultaneously from the disclosed plurality of solution storage portions, as well as from fluid ports located along the sidewalls of the Griffin reaction portion.

With respect to claim 12, Griffin and Schnipelsky disclose the apparatus in claim 11 wherein the penetration means is provided in the biochemical reaction cartridge. Figures 3-21 clearly show that a piercing pin is provided within the cartridge.

With respect to claim 13, Griffin and Schnipelsky disclose the apparatus in claim 11 wherein the penetration means is provided to the biochemical treatment apparatus. In paragraph [0014], Griffin states that the penetration means is provided in the form of extra fluid that is pumped to the chambers of the solution storage portion via the reaction treatment means.

2) Claims 6, 7, 9, 10, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin (US 20050272169) in view of Schnipelsky (US 5229297) as applied to claims 1, 8 and 11, and further in view of Vann (US 6432719).

Griffin and Schnipelsky disclose the apparatus and method set forth in claims 1, 8 and 11 as set forth in the 35 U.S.C. 103 rejections above. In paragraph [0090], Griffin teaches that the treatment sequence including the order of penetration of the partition member is regulated using a microprocessor controller. Griffin, however, does not indicate that the controller is capable of operating based on information provided by identification codes placed on the cartridge.

Vann discloses a biochemical reaction cartridge comprising a reaction portion formed by a base plate (Figure 1:22) and a frame assembly (Figure 1:46). The frame assembly is divided in such a way to provide a plurality of reaction chambers (Figure 1:32). A solution storage portion (Figure 1:42) is positioned over the reaction portion in order to move fluids stored within the storage portion to the chambers of the reaction portion using a partition member (Figure 7:278, 280). Specifically, Vann discloses in column 6, line 65 to column 8, line 11, column 10, lines 7-49 and column 11, lines 46-64 that a magnetic pinch valve is used to regulate the flow of fluid to the reaction portion from the storage portion. Operation of the cartridge is regulated by a control computer that receives information regarding the contents of the solution storage containers via identification codes printed on the solution storage containers.

Griffin and Vann are analogous art because they are from the same field of endeavor regarding biochemical reaction cartridges.

At the time of the invention, it would have been obvious to provide the cartridge disclosed by Griffin with an identification code that is reflective of the contents of each of the solution storage portion chambers. As evidenced by Vann, it is known in the art to use bar codes in an automated system to ensure that reagents are added to a reaction chamber in the correct order. The use of identification codes is effective since it allows the user to quickly determine the contents of a specific storage container and proceed according to the predetermined treatment sequence.

Response to Arguments

Applicant's arguments filed 23 July 2009 with regard to the 35 U.S.C. 103 rejections involving Griffin have been fully considered but they are not persuasive.

Applicant's principle arguments are

(a) Griffin does not disclose that the reaction portion includes a supply port on a surface facing the storage portion in a location where the storage portion is not superimposed at the time of use.

In response, please consider the following remarks.

As noted in the rejections above, Griffin discloses in paragraphs [0085] and [0086] that the reaction portion (14) includes a supply port (17) facing the storage portion (12) but not covered by the storage portion during use. The rigid frame (25) of the storage portion includes a cut out section (see Figure 1) directly over the supply port (17), thereby preventing the rigid frame from being superimposed over the supply port at the time of use. Furthermore, since the port opening (23) of the supply port (17) is

unobstructed by a flap means (24) at the time of use, the flexible part (21) of the storage portion is also not superimposed over the supply port at the time of use.

(b) One skilled in the art would not look to Schnipelsky to modify the device of Griffin because Schnipelsky teaches away from the concept of a combination of two separable portions.

In response, please consider the following remarks.

As noted in the rejections above, Griffin indicates in paragraph [0011] that fluidic ports may be positioned in either the reaction portion or the solution storage portion. Accordingly, one of ordinary skill would be motivated to add a port to a surface of the reaction portion separate from the fluid chambers of the storage portion. However, Griffin does not state if the port should be located on the reaction portion top, bottom or side surface. Schnipelsky is merely presented as evidence that fluid ports located on a sidewall of a microfluidic reaction chip are well known in the art. Since Griffin already discloses a need for a port formed on a reaction portion surface, one of ordinary skill would understand that the addition of this port would not require a complete departure from the "superposed portions principle" of Griffin.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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